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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,525	12/22/2004	Hilde Azijn	TIP0016 US	6793
27777 7590 02/07/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT	PAPER NUMBER
			1648	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/518,525

Applicant(s)

AZIJN ET AL.

Examiner

Louise Humphrey, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/10/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This Office Action is in response to the amendment filed 10 November 2006. Claims 1-10 are pending. Claims 1-4 and 7-10 are withdrawn. Claims 5 and 6 are under final rejection.

The information disclosure statement (IDS) filed on 30 June 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is considered by the examiner.

#### Claim Rejections - 35 USC § 112

The rejection of claims 5 and 6 under 35 U.S.C. §112, 2<sup>nd</sup> ¶, as being indefinite is **maintained**. The claims recite "mutation 386A," which are confusing because one does not know what strain of HIV and what protein region the number 386 is in reference to, neither is it clear what amino acid is being mutated to A.

The rejection of claims 5 and 6 under 35 U.S.C. § 112, 1<sup>st</sup> ¶, is **maintained**. The specification, while being enabling for evaluating the effectiveness of a reverse transcriptase inhibitor for HIV strains with a mutation at position 386 to alanine in the reverse transcriptase region, does not reasonably provide enablement for determining the susceptibility or effectiveness of other HIV drugs and other viral drugs in viral strains containing drug-resistant mutations other than 386A.

Applicants assert that amended claims 5 and 6 limit the detection of drug resistant mutations at position 386 in HIV reverse transcriptase. Accordingly, the rejection to claims 5 and 6 under 35 USC 112, 1<sup>st</sup> ¶ has been overcome.

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Examiner does not concur. The aspect of rejection that is maintained is the lack of enablement for a method of evaluating a change in susceptibility of an HIV drug other than reverse transcriptase inhibitor. The claimed method only determines the presence of one mutation in HIV reverse transcriptase (RT), which would only confer resistance to HIV RT inhibitors but not fusion inhibitors, protease inhibitors, and integrase inhibitors.

New Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 5 and 6 are rejected under 35 U.S.C. §102(a) as being anticipated by Margot *et al.* (14 June 2002).

The instant invention is a a method for evaluating a change in HIV drug susceptibility, comprising comparing the drug susceptibility in a sample containing the mutation 386A, from an HIV-infected patient, with a sample containing a wild type HIV reverse transcriptase.

Margot *et al.* teach a method for evaluating the virologic responses and mutational profiles in antiretroviral-experienced patients wherein HIV-1 reverse transcriptase and protease genes from plasma samples were analyzed genotypically and phenotypically. See Abstract. Margot *et al.* further teach HIV clinical isolates, MM-2239366081, MM-3576366701 and MM-4378368251, containing the mutation 386A. This genotypic change is correlated with drug-resistance as evidenced by the Stanford University HIV Drug Resistance Database. See attached database query result

(<http://hivdb.stanford.edu/cgi-bin/Reference.cgi?RefID=953&Gene=PR&Type=Clinical>). Thus, the instant invention is anticipated by Margot *et al.*

### ***Conclusion***

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

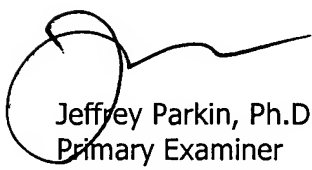
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***Contact Information***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
14 January 2007



Louise Humphrey, Ph.D.  
Assistant Examiner